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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,241	02/20/2002	Holly Hogrefe	25436/2155	7186
27495	7590	10/19/2005	EXAMINER	
PALMER & DODGE, LLP KATHLEEN M. WILLIAMS / STR 111 HUNTINGTON AVENUE BOSTON, MA 02199			HUTSON, RICHARD G	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
10/079,241	HOGREFE ET AL.	
Examiner	Art Unit	
Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-27 and 31-94 is/are pending in the application.
- 4a) Of the above claim(s) 24-27 and 31-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/1/2004 has been entered.

Applicant's amendment of claims 65, 67, 68, 70-74, 76, 86, cancellation of claims 1-23 and 69 and the addition of new claims 88-94, in the paper of 2/17/2004, is acknowledged. Claims 24-27 and 31-94 are at issue and are present for examination.

Claims 24-27 and 31-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities: Tables 2A and 2B on pages 27-28 contain a number of sequences (i.e. domain sequences) which are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) and thus require a sequence identifier (i.e. SEQ ID NO:).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65, 66, 68, 71, 73-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 73 (claims 74 and 75 dependent from) and 76 (claims 77-81 dependent from) are indefinite in the insertion of "(SEQ ID NO: 10)" into these newly amended claims. It is unclear if it is applicants intent that they are claiming an enzyme mixture comprising as a second enzyme a mutant JDF-3 polymerase in which the sequence of the mutant is SEQ ID NO: 10, or are they claiming a mutant JDF-3 polymerase in which SEQ ID NO: 10 is mutated. The confusion of applicants intent is not clarified by applicants further use of "SEQ ID NO: 10" in claim 76 when referring to a wild type JDF-3 polymerase. The confusion is further amplified since applicants only insert a sequence identifier into the claims for the JDF-3 polymerase, and not the many additional recited polymerases. While it is appreciated that applicants are trying to overcome an enablement problem with respect to the JDF-3 polymerase, it is suggested that applicants maintain consistency throughout the claims and specification.

Claims 65 (claim 66 dependent from) and 68 (claim 71 dependent from) are similarly indefinite in the recitation of "(SEQ ID NO: 10)" in the claims. It is unclear how "SEQ ID NO: 10" is used in these claims as discussed above.

Claims 68, 71 and 72 are indefinite in that they are unclear in that they all ultimately depend from claim 67, which is drawn to an enzyme mixture comprising a first

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enzyme that is a DNA polymerase and a second enzyme that is a mutant Archaeal DNA polymerase that is a mutant Pfu DNA polymerase containing specifically designated mutations. Claim 68, from which claims 71 and 72 depend, is drawn to the enzyme mixture of claim 67, wherein the "said mutant DNA polymerase comprising a mutation in its partitioning domain or polymerase domain...". There is no antecedent basis for "comprising a mutation in its partitioning domain or polymerase domain" and claim 68 further specifies that the "said mutant DNA polymerase" is a mutant Pfu, KOD, Tgo, Tli (Vent), PGB-D (Deep Vent) or JDF-3 DNA polymerase. This further specification is contradictory to the limitation of claim 67, which specifies that the mutant DNA polymerase must be a mutant Pfu DNA polymerase.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 64-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 64-94 are rejected under this statute because the limitation of claim 64 that both the first and second enzyme be a Archaeal DNA polymerase or a mutant

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Archael DNA polymerase is not supported by the specification at the time of filing and is thus considered new matter.

Claim Rejections - 35 USC § 103

The rejection of claims 64-69, 75, 82, 83 and 85-87 under 35 U.S.C. 103(a) as being unpatentable over Barnes et al. (U.S. Patent No. 5,436,149) and Komori et al. (Protein Engineering, Vol 13. No. 1, pages 41-47, 2000) is hereby withdrawn based on applicants amendment and arguments,

Double Patenting

Applicants comments in response to the previous statutory type double patenting rejection regarding the canceling of the subject matter of claims 1-3, 6, 9-11, 13-15, 19 and 21-23 are acknowledged, however it is further acknowledged that applicants along with the cancellation of claims 1-3, 6, 9-11, 13-15, 19 and 21-23, applicants added new claims 64-87 drawn to overlapping subject matter, thus necessitating a provisional nonstatutory double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 64-87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6, 9-14, 18, 20-22 and 36-51 of copending Application No. 10/035,091. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed enzyme mixtures of the instant application, comprising a first enzyme and a second enzyme wherein said first enzyme comprises a Archaeal DNA polymerase and said second enzyme is a mutant Archaeal DNA polymerase comprising a 3'-5' exonuclease activity and a reduced polymerization activity and having a mutation at an amino acid position selected from the group consisting of D405, Y410, T542, K593, Y595, Y385, Y387, and G388 and those further limited claims dependent thereon are anticipated by and thus obvious over the corresponding claims of copending Application No. 10/035,091, drawn to a enzyme mixture comprising a first enzyme and a second enzyme wherein said first enzyme comprises a DNA polymerization activity and said second enzyme is a mutant Pfu DNA polymerase having a mutation at an amino acid position selected from the group consisting of D405, Y410, T542, K593, Y595, Y385, Y387, and G388 and those further limited claims dependent thereon.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

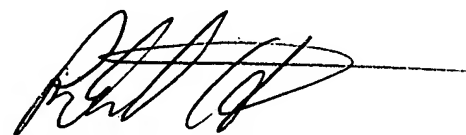
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Applicant acknowledgment of this provisional rejection is acknowledged, as well as applicants statement of their intent of filing a terminal disclaimer as a means of overcoming the rejection at the time at which the claims are found otherwise allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
10/12/2005